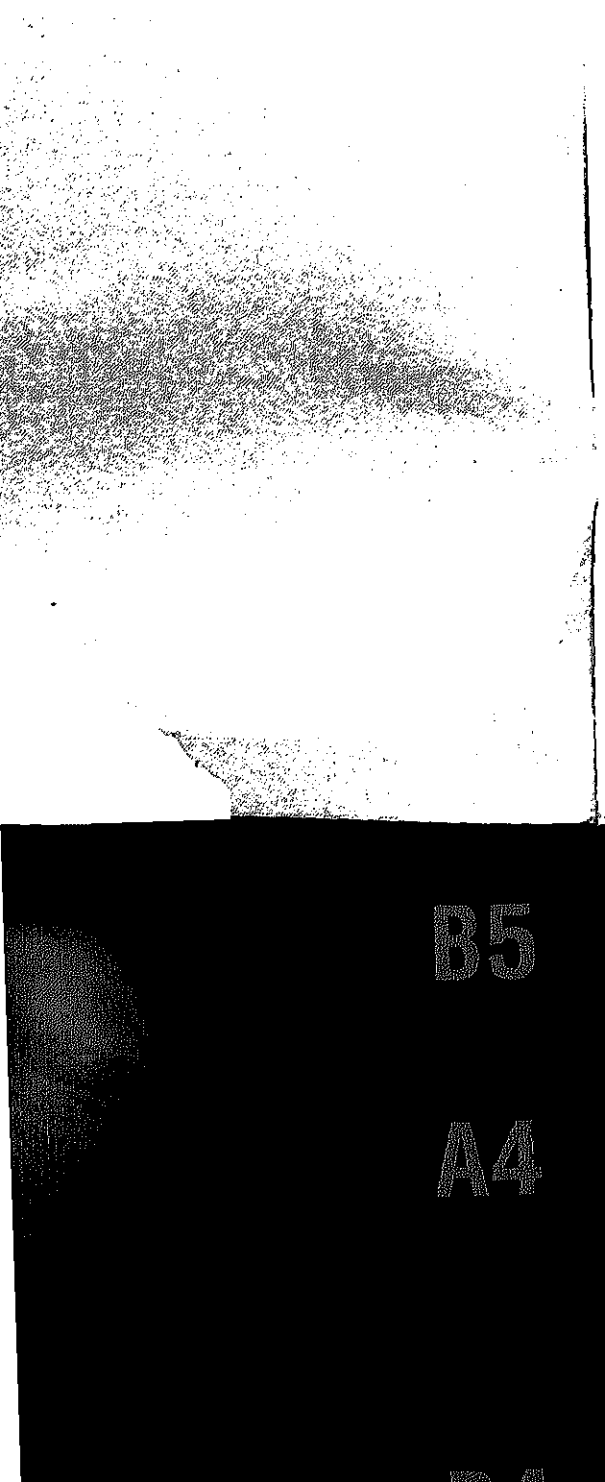
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I INTRODUCTION

1 PURPOSE

This Standard sets forth requirements for the establishment and execution of quality assurance programs for the siting, design, construction, operation, and decommissioning of nuclear facilities. Nonmandatory guidance is provided in the Appendices.

2 APPLICABILITY

The requirements of this Standard apply to activities which could affect the quality of structures, systems, and components of nuclear facilities. Nuclear facilities include facilities for power generation, spent fuel storage, waste storage, fuel reprocessing, and plutonium processing and fuel fabrication. These activities include the following:

(a) the performing functions of attaining quality objectives;

(b) the functions of assuring that an appropriate quality assurance program is established; and

(c) the function of verifying that activities affecting quality have been correctly performed

Activities affecting quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning. The application of this Standard, or portions thereof, shall be specified in written contracts, policies, procedures, or instructions.

3 RESPONSIBILITY

The organization invoking this Standard shall be responsible for specifying which Basic Requirements and Supplements, or portions thereof, apply, and appropriately relating them to specific items and services. The organization upon which this Standard, or portions thereof, is invoked shall be responsible for complying with the specified requirements.

4 DEFINITIONS

Terms used in this Standard that require unique definition are included in Supplement S-1, Terms and Definitions.

REQUIREMENT NO. 1 ORGANIZATION

The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented. Persons or organizations responsible for assuring that an appropriate quality assurance program has been established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to:

(1) identify quality problems;

(2) initiate, recommend, or provide solutions to quality problems through designated channels;

(3) verify implementation of solutions; and

(4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be effected. Such persons or organizations shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.

SUPPLEMENT 1S-1
SUPPLEMENTARY REQUIREMENTS FOR ORGANIZATION

1 GENERAL

This Supplement provides amplified requirements for organization. It supplements the requirements of Basic Requirement 1 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 RESPONSIBILITY

2.1 Purpose

The organizational structure and the responsibility assignments shall be such that:

(a) quality is achieved and maintained by those who have been assigned responsibility for performing work; and

(b) quality achievement is verified by persons or organizations not directly responsible for performing the work.

2.2 Delegation of Work

The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility therefor.

2.3 Nonconforming Items

Responsibility for the control of further processing, delivery, installation, or operation of nonconforming items shall be designated in writing

3 MULTIPLE ORGANIZATIONS

3.1 Responsibility

Where more than one organization is involved in the execution of activities covered by this Standard, the responsibility and authority of each organization shall be clearly established and documented

3.2 Interface Control

3.2.1 The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented

3.2.2 Interface responsibilities shall be defined and documented

REQUIREMENT NO. 2
QUALITY ASSURANCE PROGRAM

A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Standard, or portions thereof The program shall identify the activities and items to which it applies The establishment of the program shall include consideration of the technical aspects of the activities affecting quality The program shall provide control over activities affecting quality to an extent consistent with their importance The program shall be established at the earliest time consistent with the schedule for accomplishing the activities

The program shall provide for the planning and

accomplishment of activities affecting quality under suitably controlled conditions Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality

The program shall provide for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained

Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation

SUPPLEMENT 2S-1

SUPPELEMNTARY REQUIREMENTS FOR THE QUALIFICAITON OF INSPECTION AND TEST PERSONNEL

1 GENERAL

This Supplement provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with the Basic Requirement when and to the extent specified by the organization invoking this Standard The requirements of this Supplement do not apply to the qualification of personnel for performance of nondestructive examination

2 CERTIFICATION

2.1 Qualification Requirements

The responsible organization shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel. Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the requirements of this Supplement are permitted to perform inspection and test activities.

When a single inspection or test requires implementation by a team or a group, personnel not meeting the requirements of this Standard may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual.

2.2 Personnel Selection

Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.

2.3 Indoctrination

Provisions shall be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards and the quality assurance program elements that are to be employed.

2.4 Training

The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall also be included in the program.

with emphasis on first-hand experience gained through actual performance of inspections tests.

2.5 Determination of Initial Capability

The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's education, experience, training, and either test results or capability demonstration

2.6 *Evaluation of Performance*

The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of para 2 5 above If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated Any person who has not performed inspection or testing activities in his qualified area for a period of 1 year shall be reevaluated by a redetermination of required capability in accordance with the requirements of para 2 5 above

2.7 Certificate of Qualification

The qualification of personnel shall be certified in writing in an appropriate form, including the following information:

(a) employer's name;

(b) identification of person being certified;

(c) activities certified to perform;

(d) basis used for certification, which includes such factors as:

1 education, experience, indoctrination, and training

2. test results, where applicable

3 *results of capability demonstration*

(e) results of periodic evaluation,

(f) results of physical examinations, when required;

(g) signature of employer's designated *representative who is responsible for* such certification;

(h) date of certification and date of *certification expiration*

2.8 Physical

The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination

3 RECORDS

3.1 Record Files

Records of personnel qualification shall be established and maintained by the employer These records shall include the information required by para 2 7 above

SUPPLEMENT 2S-2

SUPPLEMENTARY REQUIREMENTS FOR THE QUALIFICATION OF NONDESTRUCTIVE EXAMINATION PERSONNEL

1 GENERAL

This Supplement provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NRT), and leak testing (LT) [hereinafter referred to as nondestructive examination (NDE)] to verify conformance to specified requirements. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 CERTIFICATION

2.1 Applicable Documents

The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 Edition, and its applicable supplements shall apply as requirements to NDE personnel covered by this Supplement.

2.2 Program

The responsible organization shall establish written procedures for the control and administration of NDE personnel training, examination, and certification.

2.3 Records

Records of personnel qualification shall be established and maintained by the employer.

SUPPLEMENT 2S-3

SUPPLEMENTARY REQUIREMENTS FOR THE QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL

1 GENERAL

This Supplement provides amplified requirements for the qualification of an audit team leader, henceforth identified as a Lead Auditor, who organizes and directs audits, reports audit findings, and evaluates corrective action. This Supplement also provides amplified requirements for the qualifications of individuals, henceforth referred to as Auditors, who participate in an audit, such as technical specialists, management representatives, and auditors-in-training. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 QUALIFICATION OF AUDITOR

2.1 Responsibility of Auditing Organization

The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs. Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the methods given in (a) through (c)following:

(a) orientation to provide a working knowledge and understanding of this Standard and the auditing organiztion's procedures for implementing audits and reporting results;

(b) training programs to provide general and specialized training in audit performance General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings

(c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits

3 QUALIFICATION OF LEAD AUDITORS

An individual shall meet the requirements of paras 3 1 through 3 4 below prior to being designated a Lead Auditor

3.1 Communication Skills

The prospective Lead Auditor shall have the capability to communicate effectively, both in writing and orally These skills shall be attested to in writing by the Lead Auditor's employer

3.2 Training

Prospective lead Auditors shall have training to the extent necessary to assure their competence in auditing skills Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor

3.2.1 Knowledge and understanding of this Standard and other nuclear-related codes,

standards, regulations, and regulatory guides, as applicable

3.2.2 General structure of quality assurance programs as a whole and applicable elements as defined in this Standard .

3.2.3 Auditing techniques of examining, questioning, evaluating, and reporting, methods of identifying and following up on corrective action items; and closing out audit findings

3.2.4 Audit planning in the quality-related functions for the following activities. Design purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility

3.2.5 On-the-job training to include applicable elements of the audit program

3.3 Audit Participation

The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to his qualification

3.4 Examination

The prospective Lead Auditor shall pass an examination which shall evaluate his comprehension of and ability to apply the body of knowledge identified in para 3.2 above. The test may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with Section 5 of this Supplement

4 MAINTENANCE OF QUALIFICATION

4.1 *Maintenance of Proficiency*

Lead Auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; or participation in training program(s) Based on annual assessment, management may extend the qualification, require retraining, or require requalification These evaluations shall be documented

4.2 Requalification

Lead Auditors who fail to maintain their proficiency for a period of 2 years or more shall require requalification Requalification shall include retraining in accordance with the requirements of para 3 2 above, reexamination in accordance with para 3 4 above, and participation as an Auditor in at least one nuclear quality assurance audit

5 ADMINISTRATION

5.1 Organizational Responsibility

Training of auditors shall be the responsibility of the employer The responsible auditing organization shall select and assign personnel who are independent of any direct responsibility for performance of the activities which they will audit The Lead Auditor shall, prior to commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

5.2 *Qualification Examination*

The development and administration of the examination for a Lead Auditor required by para 3 4 above is the responsibility of the employer The employer may delegate this

activity to an independent certifying agency, *but shall retain responsibility for conformance* of the examination and its administration to this Standard. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the employer in accordance with the requirements of Section 6 below.

6 RECORDS

6.1 General

Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer.

6.2 Certification of Qualification

Each Lead Auditor shall be certified by his employer as being qualified to lead audits. This certification shall, as a minimum, document the following:

(a) employer's name;

(b) Lead Auditor's name;

(c) date of certification or recertification;

(d) basis of qualification (i.e., education, experience, communication skills, training, examination, etc.);

(e) signature of employer's designated representative who is responsible for such certification.

6.3 Updating of Lead Auditors' Records

Records for each Lead Auditor shall be maintained and updated annually.

SUPPLEMENT 2S-4

SUPPLEMENTARY REQUIREMENTS FOR PERSONNEL INDOCTRINATION AND TRAINING

1 GENERAL

This Supplement provides amplified requirements for the indoctrination and training of personnel performing or managing activities affecting quality. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard

2 APPLICABILITY

This Supplement applies to personnel performing or managing activities affecting quality. Personnel to be indoctrinated or trained shall be identified The extent of indoctrination and training shall be commensurate with the following:

(a) the scope, complexity, and nature of the activity; and

(b) the education, experience, and proficiency of the person

Activities affecting quality include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying

3 INDOCTRINATION

Personnel shall be indoctrinated in the following subjects as they relate to a particular function:

(a) general criteria, including applicable codes, standards, and company procedures;

(b) applicable quality assurance program elements, and

(c) job responsibilities and authority

4 TRAINING

Training shall be provided, if needed, to

(a) achieve initial proficiency,

(b) maintain proficiency, and

(c) adapt to changes in technology, methods, or job responsibilities

5 RECORDS

Records of the implementation of indoctrination and training may take the form of.

(a) attendance sheets,

(b) training logs, or

(c) personnel training records

REQUIREMENT NO. 3 DESIGN CONTROL

The design shall be defined, controlled, and verified Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents Design interfaces shall be identified and controlled Design adequacy shall be verified by persons other than those who designed the item Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design

SUPPLEMENT 3S-1

SUPPLEMENTARY REQUIREMENTS FOR DESIGN CONTROL

1 GENERAL

This Supplement provides amplified require-

ments for design control It supplements the requirements of Basic Requirement 3 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard

2 DESIGN INPUT

Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled

3 DESIGN PROCESS

The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements Design documents shall be adequate to support facility design, construction, and operation Appropriate quality standards shall be identified and documented, and their selection reviewed and approved

Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented, and controlled Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for

suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. The final design (approved design output documents and approved changes thereto) shall

(a) be relatable to the design input by documentation in sufficient detail to permit design verification,

(b) identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3.1 Design Analysis

Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other data such that the calculations are retrievable.

(a) Computer programs may be utilized for design analysis without individual

verification of the program for each application provided.

(1) the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and

(2) the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application

Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on (1) and (2) above

(b) Documentation of design analyses shall include (1) through (6) below:

(1) definition of the objective of the analyses;

(2) definition of design inputs and their sources;

(3) results of literature searches or other applicable background data;

(4) identification of assumptions and indication of those that must be verified as the design proceeds;

(5) identification of any computer calculation, including computer type, computer program (e g , name), revision identification,

inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem,

(6) review and approval

4 DESIGN VERIFICATION

Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be clearly documented with the identification of the verifier clearly indicated. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent of this Standard.

Verification shall be performed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design

verification shall be completed prior to relying upon the component, system, or structure to perform its function

4.1 Extent of Design Verification

The extent of the design verification required is a function of the importance to the safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with this Standard, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven design, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design.

4.2 Methods

Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.

4.2.1 Design Reviews. These are critical reviews

to provide assurance that the final design is correct and satisfactory. Where applicable, (a) through (f) below shall be addressed.

(a) Were the design inputs correctly selected?

(b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?

(c) Was an appropriate design method used?

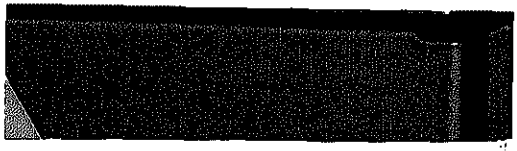
(d) Were the design inputs correctly incorporated into the design?

(e) Is the design output reasonable compared to design inputs?

(f) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?

4.2.2 Alternate Calculations. These are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed.

4.2.3 Qualification Tests. Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. odes and environmental conditions



which the item must perform satisfactorily all be considered in determining the most *iverse conditions Where the test is intended* i verify only specific design features, the other ·atures of the design shall be verified by other eans Test results shall be documented and valuated by the responsible design ·ganization to assure that test *requirements* ave been met If qualification testing indicates iat modifications to the item are necessary to btain acceptable performance, the iodification shall be documented and the item iodified and retested or otherwise verified to ssure satisfactory performance When tests are eing performed on models or mockups, scaling iws *shall be established and verified* The esults of model test work shall be subject to rror analysis, where applicable, prior to use in inal design work

. CHANGE CONTROL

:hanges to final designs, field changes, nodifications to operating facilities, and ionconforming items dispositioned use-as-is or epair shall be justified and subject to design .ontrol measures commensurate with those ipplied to the original design These measures .hall include assurance that the design analyses ·or the structure, system, or component are still valid. Changes shall be approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer *responsible, then the Owner or his designee* shall designate a new responsible organization which could be the Owner's engineering organization The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design

Where a significant design change is necessar because of an incorrect design, the desig process and verification procedure shall b reviewed and modified as necessary

6 INTERFACE CONTROL

Design interfaces shall be identified an controlled and the design efforts shall b coordinated among the participatin organizations. Interface controls shall includ the assignment of responsibility and th establishment of procedures amon participating design organizations for th review, approval, release, distribution, an revision of documnts involving desig interfaces

Design information transmitted acros interfaces shall be documented and controllec Transmittals shall identify the status of th design information or document provided anc where necessary, identify incomplete item which require further evaluation, review, o approval. Where it is necessary to initiall transmit design information orally or by othe informal means, the transmittal shall b confirmed promptly by a controlled document

7 DOCUMENTATION AND RECORDS

Design, documentation and records, whicl provide evidence that the design and desig verification processes were performed i accordance with the requirements of thi Standard, shall be collected, stored, anc maintained in accordance with documentec procedures

The documentation shall include not only fina design documents, such as drawings anc specifications, and revisions thereto but alsc documentation which identifies the importan steps, including sources of design inputs tha support the final design

REQUIREMENT NO. 4
PROCUREMENT DOCUMENT CONTROL

Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements for this Standard

SUPPLEMENT 4S-1

SUPPLEMENTARY REQUIREMENTS FOR PROCUREMENT DOCUMENT CONTROL

1 GENERAL

This Supplement provides amplified requirements for procurement document control It supplements the requirements of Basic Requirement 4 of this Standard and shall be used in conjunction with the Basic Requirement when and to the extent specified by the organization invoking this Standard

2 CONTENT OF THE PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the Purchaser.

2.1 Scope of Work

A statement of the scope of the work to be performed by the Supplier shall be in the procurement documents

2.2 Technical Requirements

Technical requirements shall be specified in the procurement documents Where necessary, these requirements shall be specified by reference to specific drawings, specifications,

codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished The procurement documents shall provide for identification of test, inspection, and acceptance requirements of the Purchaser for monitoring and evaluating the Supplier's performance

2.3 Quality Assurance Program Requirements

Procurement documents shall require that the Supplier have a documented quality assurance program that implements portions or all of the requirements of this Standard The extent of the program required shall depend upon the type and use of the item or service being procured The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents

2.4 Right of Access

At each tier of a procurement, the procurement documents shall provide for access to the Supplier's plant facilities and records for inspection or audit by the Purchaser, his designated representative, and/or other parties authorized by the Purchaser

2.5 Documentation Requirements

The procurement documents at all tiers shall identify the documentation required to be submitted for information, review, or approval by the Purchaser The time of submittal shall also be established When the Purchaser requires the Supplier to maintain specific quality assurance records, the retention items and disposition requirements shall be prescribed

2.6 Nonconformances

The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances

2.7 Spare and Replacement Parts

The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and quality assurance related data required for ordering these parts or assemblies.

3 Procurement Document Review

A review of the procurement documents and changes thereto shall be made to assure that documents transmitted to the prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements

Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review prior to contract award

Changes made as a result of the bid evaluations or precontract negotiations shall be incorporated into the procurement documents The review of such changes and their effects shall be completed prior to contract award This review shall include the following considerations:

(a) appropriate requirements specified in Section 2 of this Supplement;

(b) determination of any additional or modified design criteria;

(c) analysis of exceptions or changes requested or specified by the Supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished.

Reviews required by this Section shall be performed by personnel who have access to

pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents

4 Procurement Document Changes

Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents

REQUIREMENT NO. 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished

6 DOCUMENT CONTROL

The preparation, issue, and change of documents that specify quality requirements or prescribed activities affecting quality shall be controlled to assure that correct documents are being employed Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel

SUPPLEMENT 6S-1

SUPPLEMENTARY REQUIREMENTS FOR DOCUMENT CONTROL

1 GENERAL

This Supplement provides amplified [illegible]ements for a document control system It nents the requirements of Basic nent 6 of this Standard and shall be onjunction with that Basic Requirement

when and to the extent specified by the organization invoking this Standard

The documents which shall be controlled in accordance with this Supplement are only those documents which specify quality requirements or prescribed activities affecting quality such as instructions, procedures and drawings

The term document control used throughout this Supplementis defined as the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed

2 DOCUMENT PREPARATION, REVIEW, APPROVALS AND ISSUANCE

The control system shall be documented and shall provide for (a) through (c) below:

(a) identification of documents to be controlled and their specified distribution;

(b) identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents,

(c) review of documents for adequacy, completeness, and correctness prior to approval and issuance

3 DOCUMENT CHANGES

3.1 Major Changes

Changes to documents, other than those defined as minor changes in para 3 2 below, are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated Minor changes to documents, such as inconsequential editorial

corrections, shall not require that the revised documents receive the same review and approval as the original documents The reviewing organization shall have access to pertinent background data or information upon which to base their approval

3.2 Minor Changes

To avoid a possible omission of a required review, the type of minor changes that do not

require such a review and approval and the persons who can authorize such a decision shall be clearly delineated

REQUIREMENT NO. 7 CONTROL OF PURCHASED ITEMS AND SERVICES

The procurement of items and services shall be controlled to assure conformance with specified requirements Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion

SUPPLEMENT 7S-1

SUPPLEMENTARY REQUIREMENTS FOR CONTROL OF PURCHASED ITEMS AND SERVICES

1 GENERAL

This Supplement provides amplified requirements for control of purchased items and services It supplements the requirements of Basic Requirement 7 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard This Supplement includes requirements for source selection, bid evaluation, Supplier performance evaluation, and verification of conformance

2 PROCUREMENT PLANNING

Procurement activities shall be planned and documented to assure a systematic approach to the procurement process Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities

Planning shall determine the following:

(a) what is to be accomplished;

(b) who is to accomplish it;

(c) how it is to be accomplished;

(d) when it is to be accomplished

Planning shall be accomplished as early as practicable, and no later than at the start of those procurement activities which are required to be controlled, to assure interface compatibility and a uniform approach to the procurement process

Planning shall result in the documented identification of methods to be used in procurement activities, sequence of actions and milestones indicating the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below Planning shall provide for the integration of (a) through (i) below.

(a) procurement document preparation, review, and change control;

(b) selection of procurement sources;

(c) bid evaluation and award;

(d) Purchaser control of Supplier performance;

(e) verification (surveillance, inspection, or audit) activities by Purchaser, including notification for hold and witness points;

(f) control of nonconformances;

(g) corrective action;

(h) acceptance of item or service;

(i) quality assurance records

3 SUPPLIER SELECTION

3.1 Source Evaluation and Selection

The selection of Suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents prior to award of contract.

Procurement source evaluation and selection measures shall be implemented by the Purchaser and shall provide for identification of the Purchaser's organizational responsibilities for determining Supplier capability

Measures for evaluation and selection of procurement sources, and the results therefrom, shall be documented and shall include one or more of (a) through (c) below:

(a) evaluation of the Supplier's history of providing an identical or similar product which performs satisfactorily in actual use The Supplier's history shall reflect current capability

(b) Supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated;

(c) Suppplier's technical and quality capability as determined by a direct evaluation of his facilities and personnel and the implementation of his quality assurance program

4 BID EVALUATION

Bid evaluation shall determine the extent of conformance to the procurement documents This evaluation shall be performed by individuals or organizations designed to evaluate the following subjects, as applicable to the type of procurement.

(a) technical considerations

(b) quality assurance requirements

(c) Supplier's personnel

(d) Supplier's production capability

(e) Supplier's past performance

(f) alternates

(g) exceptions

Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable quality conditions resulting from the bid evaluation

5 SUPPLIER PERFORMANCE EVALUATION

The Purchaser of items and services shall establish measures to interface with the Supplier and to verify Supplier's performance as deemed necessary by the Purchaser The measure shall include (a) through (f) below:

(a) establishing an understanding between Purchaser and Supplier of the provisions and specifications of the procurement documents;

(b) requiring the Supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements;

(c) reviewing Supplier documents which are generated or processed during activities fulfilling procurement requirements;